



**BEFORE THE BOARD OF PATENT APPEALS & INTERFERENCES
IN THE U.S. PATENT AND TRADEMARK OFFICE**

RECEIVED
OCT 07 2003
TECH CENTER 1600/2900

In re application of:

Mark D. YANDELL

Application No. 09/619,049

Filed: July 18, 2000

For: ISOLATED DROSOPHILA PROTEINS
ESSENTIAL FOR SURVIVAL, NUCLEIC
ACID MOLECULES ENCODING ESSENTIAL
DROSOPHILA PROTEINS, AND USES
THEREOF AS INSECTICIDAL TARGETS

Art Unit: 1656

Examiner: Suryaprabha Chunduru

Atty. Docket No. CL000735

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTENTION: MAIL STOP APPEAL BRIEF - PATENTS

Sir:

This BRIEF ON APPEAL is filed, in triplicate, pursuant to a timely Notice of Appeal,
filed August 10, 2003.

REAL PARTY IN INTEREST

The application is assigned to PE Corporation (now Applera Corporation).

RELATED APPEALS AND INTERFERENCES

There does not appear to be an appeal or interference on the patent application, the
disposition of which would affect or be affected by the outcome of a decision/opinion by the

Board in this appeal.

10/06/2003 AWONDAF1 00000030 500970 09619049

01 FC:1402 330.00 DA

However, it is noted that one of the rejections cites a commonly owned pending application, to wit, the provisional obviousness-type rejection is appealed.

STATUS OF CLAIMS

Claims 4, 6, 8, and 22-26 are finally rejected. Under the statute, the Board has jurisdiction. 35 U.S.C. § 134. Specifically, the claims were rejected in the February 10, 2003 Patent Office Action (Paper No 12).

Claims 1, 3-5, 7, 9-14, and 16-20 have been canceled. The Examiner found these claims to be directed to a different invention from those on appeal, and withdrew the claims from consideration. Appellant, in turn, canceled the claims by amendment filed (by facsimile) on September 19, 2001.

STATUS OF AMENDMENT

No amendment was filed in response to the February 10, 2003 Patent Office Action.

SUMMARY OF INVENTION

The claims on appeal appear in the APPENDIX to this Brief.

Claim 4, illustrative of the claims on appeal, is directed to a molecule which is a nucleic acid selected from the group consisting of a specific nucleotide and certain nucleic acid molecules. It recites:

4. An isolated nucleic acid molecule consisting of a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO:855;

(b) a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:854;

(c) a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:853; and

(d) a nucleic acid molecule that is completely complementary to a nucleic acid molecule of (a)-(c).

Claims 22-23 are directed to individual species of nucleic acids recited in Claim 4.

Claims 6 is directed to a vector which includes the nucleic acid sequences of Claim 4. In turn, Claims 24-26 are directed to a vector of Claim 6, are restricted to the species in Claim 4, and are mutually exclusive of each other.

The present invention is based on the sequencing of the *Drosophila melanogaster* genome. Appellant's specification states that the present invention includes analysis, identification of sequence information, of previously unidentified peptides that do not share structural and/or sequence homology to any presently known proteins, peptides, or domains. Please see the specification, page 3, under heading "General Description." Furthermore, the specification states that the invention includes amino acid sequences of proteins *Drosophila melanogaster*, which are essential to the survival of the *Drosophila* species, nucleic acid sequences that encode these *Drosophila* proteins, and methods of using these proteins for insecticidal development and gene target development. In fact, the uses are described in a section of the specification bridging pages 13-18.

Because the proteins of the claims are essential to *Drosophila* survival, they can be used as insecticide targets. P-element mutation has shown that these transcripts are essential for survival. Thus, such proteins serve as excellent targets for the development of insecticidal agents. Please see pages 12-13 of the specification, second full paragraph of the Section entitled

"Protein/Peptide Uses" (last line of page 12). The specification further states at page 14, line 5, that the *Drosophila* proteins are particularly useful in insecticide screening assays, in cell-based or cell-free systems.

The specification elaborates that the proteins can be used in assays to determine the biological activity of the protein, including in a panel of multiple proteins for high-throughput screening, to raise antibodies or elicit another immune response as a reagent in assays and as markers for tissues. Please see page 13 of the specification. Another utility is use of the proteins in insecticide screening assays. Please see page 14 of the specification.

ISSUES

1. Are the Claims unpatentable for provisional obviousness type double patenting?
2. Are the Claims unpatentable under 35 U.S.C. § 101?

GROUPING OF CLAIMS

The objections/rejections pertain to all of the claims.

ARGUMENT

I. REJECTION FOR PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

A. Background

The Examiner rejected the claims in a provisional obviousness-type double-patenting rejection in view of co-pending Application No. 09/618,893 (filed July 18, 2000), entitled "ISOLATED HUMAN G-PROTEIN COUPLED RECEPTORS, NUCLEIC ACID MOLECULES ENCODING GPCR PROTEINS, AND USES THEREOF AS INSECTICIDAL

TARGETS." That application has been abandoned; however, a continuation application (No. 10/270,333) was filed on October 15, 2002.

The Examiner states that "Applicants indicated that they would delete the SEQ ID Nos. 85-87 of the copending application but did not delete said SEQ ID Nos." Please see Paper No. 12, page 2, paragraph 3. In fact, on page 1 of the Response to the Final Office Action, transmitted by facsimile to the PTO on December 3, 2002, Appellant's representative states that "Applicant will delete the SEQ ID Nos:85-87 in the claims Serial No:09/618,893, pending that claims of the present application are allowed."

The law contemplates that there are situations in which maintaining claims, rejectable for provisional obviousness double-patenting, in more than one case is an Applicant's right to maintain pendency of claimed subject matter. In In re Mott, 190 USPQ 536 (CCPA 1976), the U.S. Court of Customs and Patent Appeals authorized the concurrently pending applications containing sets of claims to interfering subject matter, stating,

"We have trouble understanding the PTO's stated rationale for making the double patenting rejection final. Once the provisional rejection has been made, there is nothing the examiner and the Appellant must do until the other application issues. We see no undue burden here. There is no question, of course, that a double patenting rejection would be proper if one of appellant's applications issues. The effect of our reversal is merely to maintain co-pendency of these claims. An affirmance under the circumstances of this case would result in the automatic abandonment of these claims upon the receipt of our mandate by the PTO since appellant has refused to cancel the corresponding claims. In re Mott, 190 U.S.P.Q. 536 (C.C.P.A. 1976).

In the instant situation, Appellant and his attorney have a reason for persisting in this case. In Appellant's view, the real issue in this appeal is the erroneous prejudicial implementation of the Patent and Trademark Office's guideline on utility in this case, as a rejection that is appealed, which is discussed in the next section. In Appellant's view, Appellant

has a right to maintain the claims in both cases to maximize the chances of obtaining coverage for the information set forth in the SUMMARY OF THE INVENTION.

II. REJECTION UNDER 35 U.S.C. § 101

Appellant respectfully traverses the rejection under 35 U.S.C. § 101. As noted in the M.P.E.P., Section 2107, the provisions of 35 U.S.C. § 101 serve at least two purposes, which an Appellant satisfies by claiming statutory subject matter and by showing that the invention is useful for some purpose. Clearly, the Patent and Trademark Office's grounds for rejection admit that the claims are for statutory subject matter.

In order to understand the issue, the expressed reasons for rejection must be compared against the "Examination Guidelines for the Utility Requirement," as set forth in the M.P.E.P., Section 2107, pages 2100-29 (Rev. 1 Feb. 2003).

A. The PTO's Express Reasons For Rejection.

The Patent and Trademark Office holds that the Appellant's cited utilities are "credible." Specifically, in Paper No. 10, the PTO states:

"Some of the cited utilities identified by the examiner are to use these nucleic acids as targets for developing insecticidal agents and to identify vertebrate and invertebrate orthologs. *These utilities are credible.*" (Paper No. 10, paragraph 5, page 3).

The most expansive expression of "reasons" for this grounds of rejection under 35 U.S.C. § 101 is set forth on page 3 of Paper No. 10, in which the Patent and Trademark Office indicates that to satisfy the Guidelines, not only an Appellant must establish to the Examiner's satisfaction that the utilities are "credible" – which the PTO admits is the case in this application

– but also the Appellant-described utilities must independently be (a) well established utilities, and (b) substantial and specific utilities. Excerpts of page 3 of Paper No. 10 are set forth below:

"These utilities are credible.....

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the nucleic acids or the underlying polypeptide.....

Given the absence of a well established utility, the final issue is whether substantial and specific utilities are disclosed in the specification....."

The Patent and Trademark Office changed its emphasis from one line of argument (in Paper No. 10) to a line of argument (at pages 3-4 of Paper No. 12), which is recited as follows:

"The instant claims are drawn to polynucleotides encoding a protein, which has no identified activity. The function of this gene and its resulting protein are as yet undetermined with no known function or activity... here the invention itself simply lacks any substantial or specific utility ." (Paper No. 12, page 4.)

B. The Examination Guidelines In Chapter 2100
Of The M.P.E.P.

In conjunction with the Examination Guidelines for the Utility Requirement, the M.P.E.P., Section 2107, pages 2100-29 (Rev. 1 Feb. 2003), states:

An invention has a well-established utility if (i) a person of ordinary skill..would immediately appreciate why the invention is useful based on the characteristics of the invention...and (ii) the utility is specific, substantial, and credible.

With respect to the "specific and substantial utility," the M.P.E.P., Section 2107, pages 2100-29 (Rev.1, 2003), equates "any particular practical purpose" to "specific and substantial utility." To explain the "specific and substantial" requirement, the M.P.E.P. states that the

requirement "excludes 'throw-away,' insubstantial, or nonspecific utilities such as the use of a complex invention as landfill."

With respect to the word "credible," the M.P.E.P. recommends assessment of credibility "from the perspective of one of ordinary skill in the art in view of the disclosure...." In Appellant's view, the Patent and Trademark Office's apparent underlying concern in this rejection is inconsistent with its policy set forth in M.P.E.P., Section 2107.01, pages 2100-33 (Rev.1, 2003, 8th Edition):

An assessment that focuses on whether an invention is useful only in a research setting thus **does not address whether the invention is in fact "useful" in a patent sense.** (M.P.E.P., Section 2102.01, pages 2100-33, August 2001, 8th Edition).

C. Appellant's Response: The Examiner Has Not Shifted The Burden Of Proof

In Appellant' view, it is important for the understanding of the rejection to note that the M.P.E.P. underscores that the guidelines are not binding and "do not constitute rule making and hence do not have the force and effect of law." M.P.E.P., Section 2100-29 (Rev.1 Feb 2003). The words in the MPEP "credible," "specific," and "substantial" are not defined. A rule of reason must be used in their interpretation.

The disclosure of utilities of the subject invention bridges pages 13-18 of the specification. The claims are restricted. The specification states, "In addition, the specific subset of genes, transcripts, and proteins are essential for survival; when altered by way of a P-element insertion, it produces a lethal phenotype."

The Examiner finds at least the following utilities "credible":

Some of the cited utilities identified by the examiner are to use these nucleic acids as **targets for developing insecticidal agents and to identify vertebrate and invertebrate orthologs. *These utilities are credible.*** (Paper No. 10, paragraph 5, page 3, emphasis added.)

In Appellant's view, there is a nexus between the identity of the claimed elements, as essential to the species' (*Drosophila*) survival, and the asserted utilities (*e.g.*, targets for insecticidal agents) found credible by the Patent and Trademark Office. This nexus would immediately be apparent to the person of ordinary skill in the art. The Patent Office has provided no evidence to establish facts to the contrary. These facts are particularly relevant to the M.P.E.P. pronouncement concerning the two-fold test for determining "well-established utility."

Clearly, the foregoing utilities are not only credible but "specific." The word "specific" is defined by the American Heritage Dictionary (Third Edition, Houghton Mifflin Company), p. 1730 (1992) as: **Specific ... 1. Explicitly set forth; definite....** In Appellant's view, the four pages of the specification relating to utility, including the description of targets for developing insecticides and for identification of orthologs, are definite, defined for a person of ordinary skill in the art.

From the excerpt of the M.P.E.P. as set forth above, the utilities found to be "credible" by the Examiner are also "substantial." Specifically, the utilities are related to the nature of the claimed subject matter, and depend on the essence of the identity of the claimed subject matter. The claimed subject matter includes nucleic acids, which are essential to the survival of the *Drosophila*. The recited utilities are not "throw-away" or "landfill."

All of the uses described in the specification, bridging pages 13-18, are related to the identity of the nucleic acids and proteins. Because the proteins of the invention are essential to *Drosophila* survival, the proteins of the invention can be used as insecticide targets. P-element mutation has shown that these transcripts are essential for survival, and thus, such proteins serve as excellent targets for the development of insecticidal agents. Please see page 13 of the specification second full paragraph in the Section entitled "Protein/Peptide Uses" (last line of page 12). Further, the specification states at page 14, line 5, that "the *Drosophila* proteins are particularly useful in insecticide screening assays, in cell-based or cell-free systems. In addition, the specification indicates that the proteins can be used in assays to determine the biological activity of the protein, including in a panel of multiple proteins for high-throughput screening, to raise antibodies or elicit another immune response, as a reagent in assays, and as markers for tissues. Please see page 13 of the specification. Moreover, the fact that one utility of the three utilities cited by the Examiner is related to use in a research context is not controlling. Please see M.P.E.P. Sections 2107.01-2100-33, under the heading "Research Tools":

An assessment that focuses on whether an invention is useful only in a research setting thus **does not address whether the invention is in fact "useful" in a patent sense.** (M.P.E.P., Section 2102.01, pages 2100-33, August 2001, 8th Edition).

In summary, although the Patent and Trademark Office has indicated proposals for making a rejection under 35 U.S.C. § 101, the rejection advanced and its reasons do not comply with the statutory provisions and their interpretation by the courts. Cf. In re F. Brana, 51 F3d. 1560 at 1566 (Fed. Cir. 1995).

In In re Brana, the court held that the PTO carried the initial burden of challenging a presumptively correct assertion of utility in the disclosure:

From this, it follows that the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure (citation omitted). Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the Appellant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. In re F. Brana, 51 F3d. 1560 at 1566 (Fed. Cir. 1995).

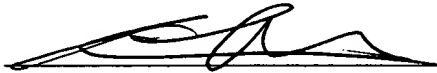
The PTO has presented no evidence that would dispute the efficacy of the claimed subject matter for either the uses found to be "credible" by the Examiner and/or described in four pages of specification bridging pages 13-18. The reasons advanced by the PTO for maintaining the rejection are inconsistent the M.P.E.P. enunciations explicating the "Guidelines." Accordingly, a rejection of claims on this appeal under 35 U.S.C. §101 constitutes *ex post facto* adjudication, prejudicially harmful to the Appellant in this appeal.

Reversal of the final rejection is respectfully solicited.

Respectfully submitted,

CELERA GENOMICS

Dated: October 2, 2003

By: 
Lin Sun-Hoffman, Ph.D.
Reg. No. 47,983

Celera Genomics,
45 west Gude Drive, C2-4#21
Rockville, MD 20850
Tel: 240-453-3628
Fax: 240-453-3084.